47. The method of claim 34, wherein said composition further comprises a local anesthetic agent.

B1

48. The method of claim 34, wherein said composition further comprises an antipruritic agent.--

REMARKS

Claims 34-48 are pending and are presented for examination. Claims 1-33 have been canceled without prejudice. As illustrated in the tables below, no new matter has been introduced with the newly added claims. For the reasons that follow, Applicants respectfully request that an interference be declared between the present application and U.S. Patent No. 6,117,877.

Relationship of the above pending claims to those in U.S. Patent No. 6,117,877

Applicants' claim 34 corresponds identically to claim 1 of U.S. Patent No. 6,117,877 ("the '877 patent"), which issued to Fogel on September 12, 2000. Claims 1–5 and 16 of the '877 patent have been written in independent form. However, claims 2-5 and 16 of the '877 patent each require all the limitations of claim 1 and therefore could have been written in a form dependent upon claim 1. The remaining claims (i.e. claims 6-22) of the '877 patent all depend from one or more of claims 1-5 and 16. Claims 6-15 are each multiply dependent from each of independent claims 1-5. Thus, each of the claims of the '877 patent are no broader than claim 1 of the '877 patent.

Applicants consider that the patentability of the subject invention lies in the treatment of anorectal disorders associated with muscle spasm by application of α-adrenergic blocking agents to the anal region. Applicants similarly consider the same to be true of the '877 claims. Thus, each of Applicants' pending claims and the '877 claims would present a novelty and/or non-obviousness bar to the patentability of each of the other party's claims depending, of course, upon their relative priority.

Applicants' claim 36, drawn to an adrenergic blocker which is an α_1-adrenergic antagonist, corresponds substantially to '877 claim 6 which is drawn to adrenergic blocker which is an α_1-adrenergic antagonist.

More particularly, Applicants' claim 37 drawn to the α_1-adrenergic antagonist doxasozin corresponds substantially to '877 claims 7 and 20, which are drawn to a Markush group of α_1-adrenergic antagonists which includes doxasozin.

More particularly, Applicants' claim 38 drawn to the α_1-adrenergic antagonist prazosin corresponds substantially to '877 claims 7 and 20, which are drawn to an antagonist selected from an α1-adrenergic antagonist Markush group that includes prazosin.

Applicants' claim 39 is drawn to methods for treating disorders selected from the group of anal fissure, anal ulcer, and anal hemorrhoid. Claim 39 thus corresponds substantially to '877 claim 13 which is drawn to a method of treating anal ulcers and to '877 claim 14, which is drawn to a method of treating thrombosed or inflamed hemorrhoids.

Applicants' claim 40 is drawn to conditions resulting from hemorrhoidal ligation or recent surgery involving the anal region substantially corresponds to '877 claim 15, which is drawn to conditions resulting from rubberband internal ligation of hemorrhoids or recent surgery in the anal region.

Applicants' claims 35 and 41 are respectively drawn to a composition further comprising a pharmaceutically acceptable carrier and a composition further comprising a topical preparation. Claims 35 and 41 thus substantially correspond to the '877 claim 11, which is drawn to mixing the composition with a cream, gel, paste, liquid, emulsion, foam, or semi-solid powder or combination thereof. Applicants' claims 35 and 41 also substantially correspond to '877 claim 12 which is drawn to a method wherein the applied composition further comprises a cream, gel, paste, liquid, emulsion, foam, or semi-solid powder or combination thereof. Applicants' claim 42 is drawn to a topical preparation selected from the group consisting of dry, liquid, cream, and aerosol formulations and therefore also substantially corresponds to '877 claims 11 and 12.

Applicants' claims 43 and 44 recite broad ranges for the relative amount of α-adrenergic blocker in the composition. The '877 patent claim 17 recites similarly broad relative amounts for two α-adrenergic blockers (doxazosin and terazosin) that overlap. Therefore, these claims substantially correspond to each other.

Applicants' claim 46 is drawn to the composition further comprising a local anesthetic. This claim is essentially identical to '877 claim 3 and substantially corresponds to claims 3-15, which through multiple dependency to claim 3, are drawn to the local anesthetic subject matter as well. Applicants' claim 46 also substantially corresponds to '877 claim 16 and its dependent

claims 17 –22. '877 claim 16 is drawn to a composition having an α-adrenergic blocker in combination with a local anesthetic and '877 claim 17 is drawn to a species of local anesthetic.

Request for Interference

Applicants respectfully request that an interference be declared under 37 C.F.R. § 1.607(a) between the present application and U.S. Patent No. 6,117,877. The present application i.e., U.S. Patent Application Serial No. 09/769621, filed January 23, 2001, is a Continuation of U.S. Patent Application No. 09/460,306 filed December 13, 1999, which claims priority to U.S. Provisional Application Nos. 60/112,325, filed December 14, 1998; 60/139,916, filed June 17, 1999, 60/155,318, filed September 21, 1999, and 60/222,267, filed July 31, 2000. The disclosure of each of which was incorporated by reference into the subject application.

Under M.P.E.P. § 2307 and 37 C.F.R. § 1.607, Applicants hereby request that an interference be declared between the present application and unexpired patent U.S. Patent No. 6,117,877 based upon an application filed on February 25, 1999. Applicants further request they be designated senior party in this interference. The present application claims priority to an application filed *prior* to the filing of the '877 patent. The '877 patent does claim priority to an earlier filed application (09/031,858 filed on February 27, 1998) which was granted on December 12, 2000 as U.S. Patent No. 6,159,944. **However, the contested subject matter of α-adrenergic blockers is not disclosed in the patentee's priority document.** The priority document makes no mention of such agents, with respect to either genus or species. A copy of the 11-page priority document U.S. Patent Application No. 09/031,858 is enclosed.

As set forth below, each of the required elements of 37 C.F.R. § 1.607 has been satisfied.

(1) The unexpired patent is U.S. Patent No. 6,117,877 . The '877 patent issued to Fogel on September 12, 2000 based upon an application filed on February 25, 1999.

(2) The proposed count is presented as follows:

COUNT 1

A method for treating a patient with a painful condition of the anal region associated with muscle spasm, the method comprising steps of:

providing a composition comprising an alpha-adrenergic blocker; and

applying an effective dose of the composition to the anal region.

Proposed COUNT 1 is the broadest method claim of the '877 patent. As is required under 37 C.F.R. § 1.606, the proposed count shall not be narrower in scope than any patent claim designated to correspond to the count.

(3) It is respectfully pointed out that all of the claims of the '877 patent correspond to the proposed count.

(4) It is respectfully pointed out that all of the claims of the instant application correspond to the proposed count.

(5) Support for claims 34-48 in the subject application is found throughout the specification as originally filed. Again, the present application, i.e., U.S. Patent Application Serial No. 09/769621, filed January 23, 2001, is a Continuation of U.S. Patent Application No. 09/460,306 filed December 13, 1999, which claims priority to U.S. Provisional Application Nos. 60/112,325, filed December 14, 1998, 60/139,916, filed June 17, 1999, 60/155,318, filed September 21, 1999, and 60/222,267, filed July 31, 2000. The disclosure of each of which was incorporated into the subject application by reference in their entireties. More particularly, in the original Application Serial No. 60/112,325, filed December 14, 1998 support is found as tabulated below. A copy of the priority document is attached herewith as an Exhibit.

6) The requirements of 35 U.S.C. § 135(b) have been met because the '877 patent issued on September 12, 2000, which is less than one year from the filing date of this Amendment which adds claims 34-48 to the above-referenced patent application.

Claim 34	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
A method for treating a patient with a painful condition of the anal region associated with muscle spasm,	As evidenced by the first sentence of the specification (page 2, 1st paragraph) the subject matter of the application encompasses methods for treating painful conditions of the anal region associated with muscle spasm: "This invention is directed to compositions and methods for treating anorectal disorders such as anal fissures, anal ulcer, hemorrhoidal diseases and levator spasm by administering to an appropriate anal area of a subject (for example, the internal anal canal) in need of such treatment a spasmolytic agent which relaxes the internal anal sphincter muscle." The anorectal disorders are defined in the specification in the paragraph bridging pages 15 and 16: "The term "anorectal disorder" includes any disorder associated with an anal rectal disease, including an acute or chronic anal fissure, an internally or externally thrombosed hemorrhoid, a hemorrhoidal disease, a disorder associated with endoscopic hemorrhoidal ligation or pain caused by such ligation, and other anorectal disorder caused by hypertonicity or spasm of the anal sphincter muscle." The above definition would encompass painful conditions of the anal region associated with spasm. The specification discloses specific subject anorectal disorders which one of ordinary skill in the art would recognize as painful in several additional places (1st sentence, 2nd paragraph, 2nd page): "In general, anal fissure (fissure-in-ano), anal ulcer, acute hemorrhoidal disease, and levator spasm (proctalgia fugax) are relatively common benign conditions of the anorectal area which affect subjects, including humans, of all ages, races, and sexes. However, these conditions can be problematical and inconvenient to treat and painful to endure." Moreover, the specification more generally discloses that anorectal disorders related to spasm that one of ordinary skill in the art would recognize as painful and discusses the role of the muscle spasm in producing various painful anorectal conditions (e.g., see first three full paragraphs on page 3) and as a source of pain itself. For example, see 3rd page, 1st full paragraph, 3rd sentence: "The patient suffering from levator spasm may experience severe episodic; rectal pain."

Claim 34	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
	See also 3rd page, 3rd paragraph, 3rd sentence: "Anal sphincter spasm is also considered a cause of pain following rectal surgery for thrombosed hemorrhoids" At page 13, last sentence the specification states: "The invention generally features a composition of and treatment for a medical conditions of the anorectal area and treatment of pain associated with such conditions (e.g., hemorrhoidal pain) and treatment of spasms and/or hypertonicity of the sphincters." The above recited use of a spasmolytic agent to treat further discloses the method is directed to anorectal disorders or conditions associated with spasm. Indeed, most of the claims of the priority application are explicitly directed to compositions and methods for treating anorectal disorders. In particular, claim 22 recites: "A method of treating an anorectal disorder, the method comprising administering to a subject in need of such treatment a therapeutically effective amount of a composition comprising an alpha-receptor antagonist, wherein said therapeutically effective amount increases or decreases hypertonicity of an anal sphincter muscle of the subject. "

Claim 34	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
the method comprising steps of : providing a composition comprising an alpha-adrenergic blocker	At page 7, last full paragraph, with respect to the above methods, the specification discloses the use of an alpha-1 adrenergic blocking agents, including various species thereof: "Prevention of the release and function of the sympathetic neurotransmitters by administering to the appropriate anal are of a subject alpha-1-adrenergic receptor antagonists (i.e.α-blockers, e.g. prazosin, doxazosin, etc. Goodman & Gilman's "The Pharmacological Basis of Therapeutics", ninth edition, ed. JG Hardman, LE Limbird, PB Molinoff, RW Ruddon, and AG Gilman, McGraw-Hill Companies, 1996) or blocking adrenergic nerves (i.e., alpha-2-agonists, e.g. clonidine, norepinephrine depleters, e.g. guanethidine, bretylin, reserpine, etc. nerve destroyers, e.g. 6-hydroxy dopamine, norepinephrine synthesis inhibitors, e.g. alpha-methyl tyrosine, etc.) may also lead to anal sphincter relaxation and improve on the signs and ymptoms of anorectal disorders.

Claim 34	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
	At page 10, line 4, the specification also discloses the use of α-adrenergic blocking agents: "In one aspect, this invention provides compositions for treating anorectal disorders which comprise an amount of an α-adrenergic antagonist effective for the relief of anal disorders (e.g., anorectal hypertonicity and/or spasms) and for improvement of the signs and symptoms of associated with anorectal disorders, e.g. anal fissures, anal ulcers and hemorrhoids. The paragraph bridging pages 17 and 18 also discloses α-adrenergic antagonists: "In one aspect, the invention provides compositions for treating anorectal disorders which comprise an active agent and a pharmaceutically acceptable carrier. The active agent comprises a spasmolytic agent, which includes an agent that stimulate or causes an increase of either cGMP or cAMP through activation of guanylyl or adenylyl cyclase, respectively, a cyclic nucleotide mimetic, PDE inhibitor, alpha-adrenergic receptor antagonist, or beta-adrenergic receptor agonist, or potassium channel opener." See also claim 22 which is directed toward alpha-adrenergic antagonists: A method of treating an anorectal disorder, the method comprising administering to a subject in need of such treatment a therapeutically effective amount of a composition comprising an alpha-receptor antagonist, ... Example 4 on page 23 discloses a base cream composition comprising the alpha-adrenergic blocking agent prazosin.

Claim 34	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
<u>applying an effective dose of the composition to the anal region.</u>	At page 10, line 8, in reference to the above recited α-adrenergic compositions, the specification provides: "The present invention also provides methods of treating anal disorders which comprise administering an effective amount of such compositions to the affected tissue or appropriate anal area (e.g., internal or external anal tissues or anal canal) of the subject in need of such treatment." The term "appropriate anal area" is defined at page 16, last 3 lines:

Claim 34	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
	"The term "appropriate anal area" means any area or tissue of the anus or sphincter that is affected by or subject to anal disorder or disease, including, for example, the external or internal anus, the external or internal anal sphincter, anal sphincter muscle, or external or internal anal canal."

Claim 35	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said composition further comprises a pharmaceutically acceptable carrier.	See page 9, first sentence paragraph bridging pages 9-10: "This invention provides compositions for treating an anorectal disorder comprising an effective amount of an α-adrenergic antagonist in a pharmaceutically acceptable carrier."

Claim 36	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said alpha-adrenergic blocker is an alpha-1-adrenergic antagonist	At page 7, last full paragraph, with respect to the above methods, the specification discloses the use of α-1 adrenergic blocking agents, including various species thereof: "Prevention of the release and function of the sympathetic neurotransmitters by administering to the appropriate anal are of a subject alpha-1-adrenergic receptor antagonists (i.e.α-blockers, e.g. prazosin, doxazosin, etc. Goodman & Gilman's "The Pharmacological Basis of Therapeutics", ninth edition, ed. JG Hardman, LE Limbird, PB Molinoff, RW Ruddon, and AG Gilman, McGraw-Hill Companies, 1996) or blocking adrenergic nerves (i.e., alpha-2-agonists, e.g. clonidine, norepinephrine depleters, e.g. guanethidine, bretylin, reserpine, etc. nerve destroyers, e.g. 6-hydroxy dopamine, norepinephrine synthesis inhibitors, e.g. alpha-methyl tyrosine, etc.) may also lead to anal sphincter relaxation and improve on the signs and symptoms of anorectal disorders.

Claim 37	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said blocker is doxazosin.	At page 7, last full paragraph, with respect to the above methods, the specification discloses the use of an α_1 adrenergic blocking agents, including various species thereof: "Prevention of the release and function of the sympathetic neurotransmitters by administering to the appropriate anal are of a subject alpha-1-adrenergic receptor antagonists (i.e.α-blockers,[e.g. prazosin, doxazosin, [emphasis added] etc. Goodman & Gilman's

Claim 37	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
	"The Pharmacological Basis of Therapeutics", ninth edition, ed. JG Hardman, LE Limbird, PB Molinoff, RW Ruddon, and AG Gilman, McGraw-Hill Companies, 1996) or blocking adrenergic nerves (i.e., alpha-2-agonists, e.g. clonidine, norepinephrine depleters, e.g. guanethidine, bretylin, reserpine, etc. nerve destroyers, e.g. 6-hydroxy dopamine, norepinephrine synthesis inhibitors, e.g. alpha-methyl tyrosine, etc.) may also lead to anal sphincter relaxation and improve on the signs and ymptoms of anorectal disorders."

Claim 38	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said alpha-adrenergic blocker is prazosin.	At page 7, last full paragraph, with respect to the above methods, the specification discloses the use of an α_1–adrenergic blocking agents, including various species thereof: "Prevention of the release and function of the sympathetic neurotransmitters by administering to the appropriate anal are of a subject alpha-1-adrenergic receptor antagonists (i.e.α-blockers [e.g. prazosin [underlining added], doxazosin, etc. Goodman & Gilman's "The Pharmacological Basis of Therapeutics", ninth edition, ed. JG Hardman, LE Limbird, PB Molinoff, RW Ruddon, and AG Gilman, McGraw-Hill Companies, 1996) or blocking adrenergic nerves (i.e., alpha-2-agonists, e.g. clonidine, norepinephrine depleters, e.g. guanethidine, bretylin, reserpine, etc. nerve destroyers, e.g. 6-hydroxy dopamine, norepinephrine synthesis inhibitors, e.g. alpha-methyl tyrosine, etc.) may also lead to anal sphincter relaxation and improve on the signs and symptoms of anorectal disorders.

Claim 39	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said condition is selected from the group consisting of anal fissures, anal ulcers, anal hemorrhoids.	As evidenced by the first sentence of the specification, the subject matter of the application encompasses methods for treating painful conditions of the anal region associated with muscle spasm: "This invention is directed to compositions and methods for treating anorectal disorders such as anal fissures, anal ulcer, hemorrhoidal diseases and levator spasm by administering to an appropriate anal area of a subject (for example, the internal anal canal) in need of such treatment a spasmolytic agent which relaxes the internal anal sphincter muscle." The anorectal disorders are defined in the specification in the paragraph bridging pages 15 and 16: "The term "anorectal disorder" includes any disorder associated with an anal rectal disease, including an acute or chronic anal

Claim 39	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
	fissure, an internally or externally thrombosed hemorrhoid, a hemorrhoidal disease, a disorder associated with endoscopic hemorrhoidal ligation or pain caused by such ligation, and other anorectal disorder caused by hypertonicity or spasm of the anal sphincter muscle."

Claim 40	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said condition results from hemorrhoidal ligation or recent surgery involving the anal region	See page 3, middle of last paragraph: "Anal sphincter spasm is also considered a cause of the pain following rectal surgery or thrombosed hemorrhoids." The anorectal disorders are defined in the specification in the paragraph bridging pages 15 and 16: "The term "anorectal disorder" includes any disorder associated with an anal rectal disease, including an acute or chronic anal fissure, an internally or externally thrombosed hemorrhoid, a hemorrhoidal disease, a disorder associated with endoscopic hemorrhoidal ligation or pain caused by such ligation [underlining added], and other anorectal disorder caused by hypertonicity or spasm of the anal sphincter muscle."

Claim 41	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said composition is a topical preparation.	See page 10, 1st sentence middle paragraph: "In another aspect, the present invention provides topical compositions useful for treating anorectal disorders (including those related to hypertonicity and/or spasm of the internal anal sphincter muscle, e.g. hemorrhoidal pain) and for treating spasms of the mammal, including humans, which comprise an effective amount of an agents that prevents the contraction of anal sphincter muscle and a pharmaceutically acceptable carrier systems." See also page 13, 1st full paragraph: "In yet another embodiment, the invention includes compositions for treating anal disorders which comprise a pharmaceutically acceptable carrier and an anal sphincter relaxing agent (e.g., a phosphodiesterase inhibitor, such as sildenafil) in an amount in the range of from approximately 0.01 to about 10 mg per 0.1 ml. The topical composition of an anal sphincter relaxing agent, e.g. a phosphodiesterase inhibitor such as sildenafil, can be applied directly to the appropriate anal area or affected area (such as the external or internal anus, anal sphincter, or anal canal). Depending

Claim 41	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
	on the concentration of the anal sphincter relaxing agent (e.g., a phosphodiesterase inhibitor, such as sildenafil) in the composition, application of the topical composition relieves hemorrhoidal pain and relaxes sphincter pressure in approximately 10 to 30 minutes." See also page 18, 2nd full paragraph: "The topical pharmaceutical compositions can also include one or more preservatives or bacteriostatic agents, e.g., methyl hydroxybenzoate, propyl hydroxybenzoate, chlorocresol, benzalkonium chlorides, and the like. The topical pharmaceutical compositions also can contain other active ingredients such as antimicrobial agents, particularly antibiotics, anesthetics, analgesics, and antipruritic agents."

Claim 42	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said topical preparation is a formulation selected from the group consisting of dry, liquid, cream and aerosol formulations.	See first two paragraphs of page 17, particularly third sentence of 1st paragraph: "Topical preparations can be prepared by combining the anal sphincter relaxing agent with conventional pharmaceutical diluents and carriers commonly used in topical dry, liquid, cream and aerosol formulations."

Claim 43	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said alpha-adrenergic blocker is present in said composition in an amount from 0.001% to about 15% by weight.	See page 18, lines 4-9: "In one aspect, the invention provides compositions for treating anorectal disorders which comprise an active agent and a pharmaceutically acceptable carrier. The active agent comprises a spasmolytic agent, which includes an agent that stimulate or causes an increase of either cGMP or cAMP through activation of guanylyl or adenylyl cyclase, respectively, a cyclic nucleotide mimetic, PDE inhibitor, alpha-adrenergic receptor antagonist [underlining added], or beta-adrenergic receptor agonist, or potassium channel opener. In one aspect, the active agent (e.g., spasmolytic agent) is present in compositions of the invention in an amount of from about 0.001% to about 15% by weight [underlining added], of the composition. In another aspect, the active agent (e.g., spasmolytic agent) is present in such compositions in an amount of from about 0.001% to about 15% by weight of the composition. In another aspect, the active agent (e.g., spasmolytic agent) is present in an amount of from about 0.01% to about 7.5% by weight or from about 0.05% to about 2% by weight of the composition."

Claim 44	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
method of claim 43 wherein said amount is from about 0.01% to about 7.5% by weight.	See immediately above.

Claim 45	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said composition future comprises an antibiotic.	See also page 18, 2nd full paragraph: "The topical pharmaceutical compositions can also include one or more preservatives or bacteriostatic agents, e.g., methyl hydroxybenzoate, propyl hydroxybenzoate, chlorocresol, benzalkonium chlorides, and the like. The topical pharmaceutical compositions also can contain other active ingredients such as antimicrobial agents, particularly antibiotics, anesthetics, analgesics, and antipruritic agents."

Claim 46	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said composition further comprises an analgesic agent.	See immediately above.

Claim 47	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said composition comprises a local anesthetic agent.	See immediately above and also see Example 8, which uses lidocaine as a local anesthetic in a topical formulation. See also next-to-last sentence of last full paragraph, page 3 for other active ingredients: "Applications of heat, cold, witch hazel, topical anesthetics, topical steroids, stool softeners, and bed rest have also been prescribed to treat rectal pain."

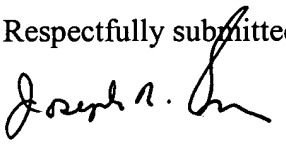
Claim 48	SUPPORT IN U.S. APPLICATION SERIAL NO: 60/112,325 FILED DECEMBER 14, 1998.
wherein said composition further comprises an antipruritic agent.	See also page 18, 2nd full paragraph: "The topical pharmaceutical compositions can also include one or more preservatives or bacteriostatic agents, e.g., methyl hydroxybenzoate, propyl hydroxybenzoate, chlorocresol, benzalkonium chlorides, and the like. The topical pharmaceutical compositions also can contain other active ingredients such as antimicrobial agents, particularly antibiotics, anesthetics, analgesics, and antipruritic agents. "

CONCLUSION

In view of the above, Applicants believe no new matter has been introduced. Applicants respectfully request that the Examiner declare an interference between the above-referenced patent application and the '877 patent, and furthermore, respectfully request that the examination of the present application be conducted with special dispatch.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



Joseph R. Snyder
Reg. No. 39,381

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, 8th Floor
San Francisco, California 94111-3834
Tel: (415) 576-0200
Fax: (415) 576-0300
JS:ldr
SF 1250893 v1

VERSION WITH MARKINGS TO SHOW CHANGES MADE

--34. (New) A method for treating a patient with a painful condition of the anal region associated with muscle spasm, the method comprising :

providing a composition comprising an α-adrenergic blocker; and

applying an effective dose of the composition to the anal region.

35. (New) The method of claim 34, wherein said composition further comprises a pharmaceutically acceptable carrier.

36. (New) The method of claim 34, wherein said blocker is an α_1-adrenergic antagonist.

37. (New) The method of claim 34, wherein said blocker is doxasozin.

38. (New) The method of claim 34, wherein said blocker is prazosin.

39. (New) The method of claim 34, wherein said painful condition is selected from the group consisting of anal fissures, anal ulcers, and anal hemorrhoids.

40. (New) The method of claim 34, wherein said painful condition results from hemorrhoidal ligation or recent surgery involving the anal region.

41. (New) The method of claim 34, wherein said composition is a topical preparation.

42. (New) The method of claim 41 wherein said topical preparation is a formulation selected from the group consisting of dry, liquid, cream and aerosol formulations.

43. (New) The method of claim 34, wherein said α-adrenergic blocker is present in said composition in an amount from about 0.001% to about 15% by weight.

44. (New) The method of claim 43 wherein said amount is from about 0.01% to about 7.5% by weight.

45. (New) The method of claim 34, wherein said composition further comprises an antibiotic.

46. (New) The method of claim 34, wherein said composition further comprises an analgesic agent.

47. (New) The method of claim 34, wherein said composition further comprises a local anesthetic agent.

48. (New) The method of claim 34, wherein said composition further comprises an antipruritic agent.--